Med Supplies (368370620207201) One lot consisting of 3-Ea Cook Endoscopic Ultrasound Needle 19 Stock # G31520 Exp: 08/2016; 2-Ea Cook HD Ultrasound Biopsy Needle 25-C Stock # G255738 Exp: 12/2016; 2-Ea Barrx Medical Inc. Halo Guidewire Stock # GW-002B Exp: 01/2017; 1-Bx Given Imaging Inc. Catheter Kit/Clinical Kit Stock # MSS-2155 Exp: 8/2016; 1-Ea Barrx Medical Halo 360+Ablation Catheter Stock #32041-25 Exp: 11/2016; 4-Ea Barrx Medical Inc. Halo 360+ Sizing Balloon Stock # 3441C Exp: 11/2016; 4-Ea Boston Scientific Eus Aspiration Needle 22 Ga Stock # 5001 Exp: 11/2016. All are in new/like new/unused condition and none are expired yet. The doctor who used these items is no longer here and no one else uses them.
** Winning bidder required to complete and submit the attached "71QSCI16501020 Medical Devices SOI.pdf" prior to removal. E-mail to mark.maxwell@gsa.gov with a Cc to tina.wimberly@va.gov is the preferred method of submission**

MEDICAL DEVICES. Purchasers of all medical equipment listed in the Invitation for Bid (IFB) shall certify and assure in writing that such item will b e used or resold only under the conditions specified below:

Medical device items are subject to the laws and regulations administered by the Food and Drug Administration (FDA). Provisions of the governing statute, the Federal Food, Drug and Cosmetic Act appear in 21 U.S.C. 331, ET. Seq. In summary, the Act prohibits the movement in interstate commerce of medical devices that are misbranded or adulterated. The Act authorizes FDA to initiate criminal enforcement proceedings against companies and/or individuals responsible for violations of its provisions. Moreover, the Act authorizes FDA to initiate civil proceedings to seize, or enjoin the distribution of such items.

It shall, also, be the responsibility of all purchasers to comply with local, state, or other applicable laws.

The following certificate, to be a separate attachment to the Invitation for Bid, is required by FDA to purchase the medical device items identified in the Invitation.

I certify that I am a licensed practitioner and/or other person regularly and lawfully engaged in the manufacture and/or refurbishing of the medical device item identified in the IFB. I, also, certify that prior to sale or use of such a device, I will take assurance that such a device is not adulterated or misbranded within the meaning of those terms in the Federal Food Drug and Cosmetic Act (21 U.S.C., et Seq.).

_____ _____

Signature **Date**

Recognizing that Federal law places stringent restrictions on adulterated or misbranded medical devices (21 U.S.C. 331, et. Seq.), I certify that I either will sell or otherwise proffer the medical device item identified in the IFB to persons described in the above, or will not use this item(s) for their original or usual intended use, for any other medical use.

_____ _____

Signature **Date**

False or misleading statements may result in a fine of not more than $10,000 or imprisonment for not more than five (5) years, or both (18 U.S.C. 1001).